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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,285	10/25/2005	Koji Nashimoto	280145US0PCT	3149

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EXAMINER

MARTIN, PAUL C

ART UNIT	PAPER NUMBER
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1657

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/554,285

Applicant(s)

NASHIMOTO ET AL.

Examiner

Paul C. Martin

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☒ Claim(s) 5-7 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/25/06</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 1-7 are pending in this application.

Claims 5-7 were not examined on their merits due to the objection set forth below.

Claims 1-4 were examined on their merits.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on 04/08/2003. It is noted, however, that applicant has not filed a certified copy of the Japan 2003121701 application as required by 35 U.S.C. 119(b).

Claim Objections

Claims 5-7 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

The Examiner notes that Claims 5 and 6 further contain "use of" language and advises the Applicant that maintenance of this language may necessitate rejection of those claims under 35 USC § 101 in the next Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Madsen *et al.* (US 5,741,662).

Madsen *et al.* teaches a staining agent for the detection of *Candida* fungal pathogens comprising applying a staining agent containing the xanthene dye Rhodamine 6G and sodium hydroxide (an alkali substance) to a sample of *Candida* cells and detecting the stained cells (Column 15, Lines 43-67 and Column 16, Lines 1-43).

Madsen *et al.* teaches the detection of bacteria using the staining agent (Column 17, Claim 1 and Column 5, Lines 26-27), the use of the xanthene dye Rhodamine B (Column 7, Line 45), the use of the diazo dye Trypan Blue for whole cell staining (Column 2, Line 23) and the use of the diazo dye Sudan Black B as a stain for poly- β -hydroxybutyric acid (PHB) (Column 6, Lines 49-51).

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Hurley *et al.* (US 4,940,834).

Hurley *et al.* teaches a method of staining fungus with a staining agent comprising sodium hydroxide and Trypan Blue (Column 5, Lines 21-31).

Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by Chae *et al.* (US 2003/0171556 A1).

Chae *et al.* teaches a method of staining β -amyloid in tissue samples with a staining agent comprising sodium hydroxide and Congo Red (Pg. 18, Paragraph [0200]). Though the stain used by Chae *et al.* was not instantly used to stain microorganisms, it is not precluded for use as a microorganism staining reagent.

Art Unit: 1657

Applicant is asked to review *In re Hack*, 245 F.2d 246, 248,114 USPQ 161, 163 (CCPA 1957). When the claim recites using an old composition or structure and the use is directed to a result or property of that composition or structure, then the claim is anticipated (MPEP 2100 pp. 2113).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madsen *et al.* (US 5,741,662) in view of Kass (4,853,210) and Ostle *et al.* (1982).

The teachings of Madsen *et al.* were discussed above.

Madsen *et al.* does not teach a microorganism staining agent wherein the diazo dye is selected from the group consisting of Chicago Sky Blue 6B, Evans Blue, Direct Blue 15, Trypan Blue, Benzopurpurin 4B and Congo Red, and further comprising methanol and/or dimethyl sulfoxide.

Kass teaches a method of staining cells with a cationic diazo dye, Basic Blue 93 wherein the staining agent comprises methanol as a fixative (Column 4, Lines 19-36) and the use Sudan Black B diazo dye lipid stain (Column 3, Lines 3-8).

Ostle *et al.* teaches that Sudan Black is a known stain for PHB, which is used as an energy source and carbon reserve in prokaryotes (Pg. 238, Column 1, Lines 1-8). It would have been obvious to one of ordinary skill in the art at the time of the instant invention to adapt the microorganism staining agent comprising a xanthene dye and sodium hydroxide as taught by Madsen *et al.* with the use of a staining agent comprising a diazo dye and methanol as taught by Kass because Madsen *et al.* also teaches the use of diazo dyes for staining cells. One of ordinary skill in the art would have recognized that Chicago Sky Blue 6B, Evans Blue, Direct Blue 15, Trypan Blue, Benzopurpurin 4B and Congo Red were functional equivalents of the diazo dye Sudan Black B, a known bacterial stain as disclosed by Ostle *et al.* above. The use of alternatives and functional equivalent techniques would have been desirable to those of ordinary skill in the art based upon the economics and availability of compounds. Further, one of skill in the art would have been motivated to use a staining agent comprising methanol as taught by Kass because the use of methanol as a fixative for preservation of cell structures and would have been within the purview of one of ordinary skill in the art. There would have been a reasonable expectation of success in making this change because both methods are drawn to methods of direct cellular staining using xanthene or diazo dyes.

Art Unit: 1657

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1657

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin
Examiner
Art Unit 1657

10/30/06



PATRICIA LEITH
PRIMARY EXAMINER